

### REMARKS

The claims are 1, 2, 7-18, 20-25, 28-30 and 34. Claims 1, 2, 11, 24, and 34 are in independent form. Favorable reconsideration is respectfully requested.

In the Office Action, all of the prior rejections under 35 U.S.C. § 103(a) are maintained, with Claims 1, 2, 7-18, 22, 23, 28-30 and 34 alleged to be unpatentable over *Winskill et al.*, Animal Behavior Science 48:25-35 (1996) in view of *Johnson et al.*, Equine Veterinary Journal 30(2): 139-143 (1998), further in view of *Pagan*, Australian Equine Veterinarian 16(4): 159-161 (1998). Claims 20 and 21 are now also included in the rejection. Claims 24 and 25 remain rejected under § 103(a) as allegedly unpatentable over *Johnson et al.*, and *Winskill et al.*, in view of *Pagan*. Applicants respectfully traverse these rejections and incorporate by reference all the previously advanced arguments.

The Examiner has made the Office Action final asserting that the “Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action, the inclusion of claims 20 and 21 with the rejection in light of the amendment of the claims to reflect oral administration.” Office Action, page 8. However, the Applicants believe the final rejection is premature.

“Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims nor based on information disclosure statement filed . . . .” MPEP § 706.07(a). In the present case, new ground of rejection of Claims 20 and 21 was neither based on information disclosure statement nor necessitated by Applicants’ amendment to Claims 20 and 21. In the Office Action dated April 6, 2006, the Examiner considered that the subject matter of these claims to be allowable if rewritten in independent form including all the limitations of the base Claim

34. Hence, the Applicants do not understand why the Examiner has rejected the subject matter of Claims 20 and 21 after the scope of these claims has been narrowed by virtue of a clarifying amendment to Claim 34 specifying that the composition is orally administered to the animal. In addition, in the Amendment dated October 6, 2006, Applicants pointed out the patentable novelty of the narrowing amendment to Claim 34. Thus, it is respectfully submitted that the finality of the rejection is premature and should be withdrawn.

In the "Response to Arguments" section, the Examiner asserts that:  
"Johnson orally feed the horses with hay and therefore, administration of the antacid sodium carbonate is by way of oral feed." Office Action, page 6.

Applicants believe that the Examiner has misunderstood the *Johnson* disclosure. As far as the Applicants are aware, there is no disclosure that *Johnson* orally feed horses with sodium carbonate. In fact, the description of the trials carried out by *Johnson* contains no disclosure of any administration of sodium carbonate to horses. See *Johnson*, page 140, left column, "Feeding". *Johnson*'s reference to administration of sodium carbonate is in the "Introduction" section, where it cites a study by *Willard et al.* (1977), and states that the sodium carbonate was administered to the caecum in this study. *Johnson*, page 139, right column. The disclosure of *Willard* confirms that administration of sodium carbonate was by caecal infusions through a caecal fistula, not by oral administration. *Willard*, page 87, right column, "Experimental Procedure".

The Examiner further asserts that "Since the carbonate in *Johnson* produces the desired effect when orally administered, then addition of the carbonate to the feed of Winskill would also produce the desired effect and examiner does not see the inconsistency applicant refers". Office Action, pages 6-7.

Applicants respectfully submit that the Examiner's statement is incorrect. Since *Johnson* does not administer carbonate (either orally or by other means), the effect produced in *Johnson* is not caused by carbonate. The Examiner's conclusion that addition of carbonate to the feed of *Winskill* would also produce the desired effect appears, therefore, to be based on a misunderstanding of the disclosure of *Johnson*, and of Applicants' arguments. Applicants again respectfully point out to the Examiner that disclosure by *Willard* (referred to in *Johnson*), is that sodium carbonate is administered to the caecum (part of the hindgut) by caecal infusion to neutralize hindgut acidity, not by oral administration. One of ordinary skill in the art would not have combined sodium carbonate with the feed of *Winskill* to affect behaviour based on the teaching of *Johnson* (referring to *Willard*) because the sodium carbonate would need to be administered separately from the feed (i.e. to the caecum by caecal infusion).

The Examiner also asserts that "Johnson observes that both the carbonate and the Founderguard lead to a reduction in stereotypic behavior". Office Action, page 7.

However, Applicants believe that it is clear from the disclosure of *Johnson* that the effects of carbonate and Founderguard are believed to be the result of reduced acidosis in the hindgut: "neutralizing the acidity of the hind-gut ... by administering sodium carbonate to the caecum lowered the incidence of stereotypic behaviour" (page 139, right column); "Administration of Founderguard led to a dramatic reduction in abnormal behaviour . . . . The most obvious explanation of the effects is that suggested by the work of Willard et. al. (1977), that is, reduced acidosis in the hindgut" (page 143, left column). Applicants respectfully submit that there is no disclosure in *Johnson* of a link between stomach acidity and stereotypy.

The Examiner alleges that “Johnson recognizes the relationship of acidity and stereotypy and specifically notes that lowering of acidity leads to reduction in stereotypy.” Office Action, page 7, paragraph (b).

Applicants believe the Examiner is oversimplifying the disclosure of *Johnson*. *Johnson* recognizes the relationship between acidity in the hindgut and stereotypy, but does not disclose any link between stomach acidity and stereotypy: “The most obvious explanation of the effects is that suggested by the work of Willard et al. (1977), that is, reduced acidosis in the hindgut”. *Johnson*, page 143, left column.

The Examiner further asserts that “it flows that reduction in the acidity of the intestinal tract would lead to reduction in stereotypy”. Office Action, page 7.

Applicants believe the Examiner's statement that there is a reduction in the acidity in the intestinal tract is again an oversimplification. *Johnson* only discloses reduced acidosis in the hindgut. This is only a part of the intestine. Applicants have previously pointed out that the hindgut (which consists of the colon and the caecum) is separated from the stomach by the small intestine. See *Kohnke* (1998) cited in the response to the Office Action of February 26, 2003. A relationship between hindgut acidity and stereotypy does not mean that there is also a relationship between acidity in the small intestine and stereotypy, or between stomach acidity and stereotypy.

The Examiner then asserts that “Applicant addresses the individual references and does not consider the combined references.” Office Action, page 7.

Applicants respectfully disagree. Applicants have explained in previous responses why the cited references do not render the claimed subject matter obvious when considered in combination. See, for example, pages 10-13 of the Applicants' Amendment dated October 6, 2006. In particular, *Johnson* discloses a link between hindgut acidity and

stereotypy, whereas *Winskill* teaches that stereotypies may result from an inability to express foraging behaviour, but contains no disclosure of a link between pH generally and stereotypies. Even if a person skilled in the art combined the teaching of *Johnson* with the teaching of *Winskill*, they would not arrive at the claimed subject matter. Neither caecal administration of carbonate, nor oral administration of Virginiamycin is expected to control stomach acidity. As Applicants understand it, *Pagan* relates only to the treatment of equine gastric ulcers, and contains no reference to stereotypy. The histamine type-2 antagonists disclosed in *Pagan* are believed to act as stomach antacids, not hindgut antacids, and so would not be used by a person skilled in the art in place of oral administration of Virginiamycin or caecal administration of carbonate to reduce hindgut acidity.

Regarding the Declaration of Patricia Harris filed with the Applicants' Amendment dated October 6, 2006 response ("the Harris Declaration"), the Examiner states that: "Applicant appears to be casting doubt on the disclosure of the prior art teaching that Founderguard and carbonate and histamine type-2 antagonists reduce acidity and stereotypy". Office Action, page 8.

Applicants are not trying to cast doubt on what is disclosed in the cited references. Applicants simply disagree with the Examiner's assertion about what the cited references disclose. In particular, the Examiner asserts that "the prior art teach[es] that . . . histamine type-2 antagonists reduce acidity and stereotypy". *Id.* Applicants believe that this statement is not correct. As far as Applicants are aware, there is no disclosure in any of the cited references that histamine type-2 antagonists reduce stereotypy. Applicants respectfully request the Examiner to point to explicit disclosure in the cited references that histamine type-2 antagonists reduce stereotypy in order to support the Examiner's assertion.

The Examiner also asserts with regard to the composition claims that intended use of the composition does not patentably distinguish the claimed composition over the composition of the prior art. *Id.*

Applicants are not attempting to distinguish the claimed compositions from those disclosed in the cited references on the basis of their intended use, but instead on whether a person skilled in the art would have made such compositions based on the teaching of the cited references at the priority date of the present application. The carbonate disclosed in *Willard* (referred to in *Jonhson*) was administered by caecal infusion to affect hindgut pH, not by oral administration. One of ordinary skill in the art would not have combined the carbonate of *Willard* (referred to in *Johnson*) with the feed of *Winskill* since (for reasons explained above) oral administration of carbonate would not be expected to affect hindgut pH. The Founderguard disclosed in *Johnson* is not believed to be a stomach antacid, so even if the skilled person combined the Founderguard of *Johnson* with the feed of *Winskill*, a composition as claimed would not have been formed. In addition, a person skilled in the art would not have substituted the carbonate of *Willard* (referred to in *Johnson*), or the Founderguard of *Johnson*, with the antacid of *Pagan* because the antacid of *Pagan* is not believed to affect hindgut pH and there is no disclosure in any of the cited documents that controlling stomach pH rather than hindgut pH affects stereotypy.

The Examiner has rejected Claims 20 and 21 in view of the amendment to Claim 34, specifying that the composition is orally administered. The Examiner cites *Winskill et al*, *Johnson et al*, and *Pagan*, and asserts that “since it is known in the prior art that carbonate antacid reduces stereotypy, it would be obvious to one of ordinary skill in the art at the time the invention was made to include carbonate or Founderguard in the animal's feed from birth or in the diet of a lactating mother.” Office Action, page 2.

Applicants submit that Claims 20 and 21 are patentably distinct from the cited prior art for at least the following reasons.

The carbonate disclosed in *Willard* (referred to in *Johnson*) was administered by caecal infusion (see *Willard*, page 87, right column, "Experimental Procedure") not by oral administration, thereby affecting hindgut acidity not stomach acidity. If a person skilled in the art wanted to minimize the risk of an animal developing stereotypy based on the teaching of *Willard* (referred to in *Johnson*), the skilled person would have administered carbonate by caecal infusion to reduce hindgut acidity, not stomach acidity, and so would not have administered carbonate orally. Evidence against oral use of carbonate to reduce hindgut acidity in the horse was included in the Harris Declaration.

With regard to Founderguard, Applicants believe that a person skilled in the art would not even administer Founderguard to an animal from birth, or to the diet of the animal's mother while she is lactating. It is thought that young animals, such as foals, need to establish bacteria in their hindgut for normal health. Administration of Founderguard would appear to be counterproductive, since this is effective against bacteria in the hindgut (Virginiamycin, an antibiotic in Founderguard, is specifically active against bacteria that ferment carbohydrate) and might be expected to be harmful to a young animal. Furthermore, as explained in the Harris Declaration, the Founderguard disclosed in *Johnson* is believed to affect hindgut acidity, not stomach acidity, and so Founderguard is not considered to be a stomach antacid. As far as the Applicants are aware, no one has ever suggested that oral administration of Founderguard would affect stomach acidity. Accordingly, Founderguard is not considered to be a stomach antacid, nor to control stomach pH, as required by Claim 34.

As Applicants have previously made clear on page 7, last paragraph, to page 13 of the Amendment dated October 6, 2006, nothing in the cited prior art teaches or suggests either a link between stomach acidity and stereotypy generally, or orally administering a composition comprising fat, fibre, and optionally a stomach antacid, to control stomach pH and thereby treat or ameliorate stereotypy, or minimize the risk of an animal developing animal stereotypy.

In particular, as Applicants understand it, *Winskill* relates to the effect of a foraging device on the behavior of the stabled horse, and that a feed of fibre and oil provided with the foraging device (a Foodball) reduces time spent standing and increases foraging time. There is no disclosure in *Winskill* of any link between pH generally and stereotypies, and none of the horses used in the experiment described were seen to perform stereotypic behavior.

*Johnson* does not remedy the deficiencies of *Winskill*. *Johnson* discloses a correlation only between hindgut pH and abnormal behavior. Referring to *Willard et al.* (1977), *Johnson* discloses that "neutralising the acidity of the hind-gut of such animals by administering sodium carbonate to the caecum lowered the incidence of stereotypic behaviour." *Johnson*, page 139, right column. It is concluded from the separate study described in *Johnson* that administration of Founderguard led to a dramatic reduction in abnormal behaviour. The most obvious explanation of these effects is concluded to be reduced acidosis in the hindgut: "The primary mechanism of virginiamycin, the active ingredient of Founderguard, is to suppress lactic acid production from starch fermentation in the hindgut". *Id.* at page 143. The teaching of *Johnson* is limited only to correlating hindgut acidity with abnormal behavior. One of ordinary skill in the art would not have combined sodium carbonate with the feed of *Winskill* because sodium carbonate was



administered directly to the caecum to neutralize hindgut acidity (by *Willard*), and so would need to be administered separately from the feed. If Founderguard was combined with the feed of *Winskill*, this would not form a composition comprising a stomach antacid because Founderguard is not believed to affect stomach acidity.

*Pagan* also does not remedy the deficiencies of *Winskill* and likewise fails to recognize any link between stomach pH and stereotypy. There is not even any reference to stereotypy in *Pagan*. *Pagan* relates only to the treatment of equine gastric ulcers. One of ordinary skill in the art would not have administered the antacids of *Pagan* because none of the antacids disclosed in *Pagan* would be expected to have any effect on hindgut acidity, and there is no disclosure in any of the cited documents that there is any relationship between stomach pH and stereotypy.

In sum, nothing in the cited art is believed to teach or suggest either a link between stomach acidity and stereotypy generally or providing a composition with a stomach antacid, fat and fiber as specifically recited in the present claims. Based on the foregoing, Applicants therefore submit that Claims 1, 11 and 34, together with the claims dependent thereon, are patentable over *Winskill* and *Johnson*, further in view of *Pagan*. Independent Claims 2 and 24, together with the claims dependent thereon, are likewise believed patentable by virtue of at least the same reasons advanced above. Accordingly, withdrawal of the present rejections is kindly requested.

Wherefore, it is respectfully submitted that the presently claimed invention is not disclosed or suggested by the art of record whether taken alone or together. Accordingly, it is respectfully requested that the claims be allowed and the case passed to issue.

Applicants' undersigned attorney may be reached in our New York Office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address listed below.

Respectfully submitted,



Raymond R. Mandra  
Attorney for Applicants  
Registration No.: 34,382

FITZPATRICK, CELLA, HARPER & SCINTO  
30 Rockefeller Plaza  
New York, New York 10112-3801  
Facsimile: (212) 218-2200

FCBS\_WS 1426846v1